

**K234109 Ziehm Solo FD**Jan 26, 2024  
30 days to decisionK234109 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k234109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 27, 2023
Decision date	Jan 26, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ziehm Imaging GmbH</b>
Location	Orlando, FL, US
Contact	Tsvetelina Milanova
510(k) history	18 submissions · 18 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234109/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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